



(19) Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) EP 0 567 029 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention
of the grant of the patent:
05.03.1997 Bulletin 1997/10

(51) Int. Cl.⁶: A61M 25/02

(21) Application number: 93106287.1

(22) Date of filing: 19.04.1993

(54) **Repositional catheter fixation device**

Wiederverwendbare Befestigungsvorrichtung für Katheter

Dispositif réutilisable de fixation pour cathéter

(84) Designated Contracting States:
DE FR GB IT SE

• Powelson, Gerald D.
American Fork, Utah 84003 (US)
• Crawford, Mark
Sandy, Utah 84070 (US)

(30) Priority: 24.04.1992 US 873903

(74) Representative: Bosotti, Luciano et al
c/o JACOBACCI & PERANI S.p.A.
Corso Regio Parco, 27
10152 Torino (IT)

(43) Date of publication of application:
27.10.1993 Bulletin 1993/43

(56) References cited:
US-A- 3 574 306 US-A- 3 834 380
US-A- 3 896 527 US-A- 4 699 616

(73) Proprietor: Becton Dickinson and Company

Franklin Lakes, New Jersey 07417-1880 (US)

(72) Inventors:

• Orr, Douglas P.
Sandy, Utah 84093 (US)

EP 0 567 029 B1

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description**BRIEF DESCRIPTION OF THE DRAWINGS****BACKGROUND OF THE INVENTION**

The invention relates to fixation devices for securing tubing such as catheter tubing to a patient undergoing medical treatment. 5

During medical procedures such as surgery, it is often necessary to infuse medication into a patient or monitor the condition of a patient via tubing such as intra-venous catheter tubing. At least part of such tubing lies outside of the patient and must be secured to avoid entanglement or crimping which may impede the infusion or monitoring process. 10

SUMMARY OF THE INVENTION

The present invention relates to a device for holding tubing such as intravenous catheter tubing or the like to a patient. The device comprises two lobes. Each of the lobes is made up of two tabs and of two semi-cylindrical members each comprising a gripping channel. Such a device is known, e.g. from US-A-3 574 306 or US-A-3 834 830. In the arrangement of the invention, which has the features set forth in Claim 1, the inner surface of at least one of the channels is provided with a gripping means which is specially adapted for gripping the tubing. The tubing is gripped between the two channels when the two lobes are brought together and the tabs touch each other. The device is provided with a connector which holds the lobes together so that the channels can grip the tubing. 15

In a preferred embodiment, a hinge is interposed between the two lobes so that the lobes can be rotated about the hinge between an open position and a closed position. When the lobes are brought together, the tabs touch. The tubing is gripped between the channels in the closed position. The tabs are designed so that at least one tab will overlap the other. In order to secure the device to a patient at least one of the tabs is provided with a suture hole. 20

The gripping means may have several embodiments. It may have a contoured gripping surface or it may comprise a tacky material which is designed to grip the tubing. The contoured surface may be sinusoidal, roughened uneven or it may be made up of a plurality of bumps. The gripping means may also be made up of a liner which likewise may be made of a tacky material or contoured as described above. 25

When the lobes are joined, the inside diameter of the tube formed by the channels is typically slightly smaller than the outside diameter of the tubing so that the tubing is gripped by the device without undue constriction. When the lobes are joined a portion of one tab overlaps the other, facilitating suturing and separation of the tabs. 30

The invention will be further understood by reference to the following drawings and description.

Fig. 1 is a perspective view of the preferred embodiment of the invention in its closed state; 5

Fig. 2 is a top view of the preferred embodiment of the invention in its open state;

Fig. 3 is a bottom view of the preferred embodiment of the invention in its open state;

Fig. 4 is a side view of the preferred embodiment of the invention in its open state;

Fig. 5 is a front view of the preferred embodiment of the invention in its closed state;

Fig. 6 is a top perspective view of the preferred embodiment of the invention in its open state, showing the liner removed;

Fig. 7 is a cross-sectional view through section 7-7 showing the contour of the inside of the liner;

Fig. 8 is a top perspective view of an alternate embodiment of the liner of the invention;

Fig. 9 is a top perspective view of an alternate embodiment of the invention which does not have a liner. 10

DETAILED DESCRIPTION

In the following detailed description of the preferred embodiment, reference is made to the accompanying drawings. The description shows by way of illustration a specific preferred embodiment of the invention. This embodiment is described in sufficient detail to enable those skilled in the art to practice the invention. It is to be understood that other embodiments may be utilized and that structural changes may be made without departing from the scope of the present invention as defined in the annexed claims. The following detailed description is, therefore, not to be taken in a limiting sense. The scope of the present invention is defined by the appended claims. 20

Fig. 1 is a perspective view of fixation device 10 in

40 its closed state showing tubing 12 passing through tube gripping lumen 14. The two lobes 16, 18 of fixation device 10 are clipped together by means of snap-connector 22 to form fin 20. Lobes 16 and 18 are preferably made of polypropylene. The preferred grade is PF091B 45 supplied by Hilmont USA, Inc. However, any polypropylene which is suitable for forming a hinge between lobes 16 and 18 may be used. Lobes 16 and 18 comprise tabs 24 and 26 respectively and semi-cylindrical channels 28 and 30 respectively. Suture holes 32 and 34 are provided in tabs 24 and 26 respectively. Channels 28 and 30 form a generally cylindrical tube holder 38 having a tube gripping lumen 14, a first end 40 and a second end 42. Ends 40 and 42 protrude slightly outwards of fin 20.

50 Grooves 44 and 46 are provided in end portions 40 and 42 respectively. Grooves 44 and 46 may be used to hold fastener 10 to the skin by means of sutures. Tabs 24 and 26 are provided with overlap portions 48 and 50 respectively. These provide leverage to facilitate the disengagement of snap-fit connector 22, as well as provid-

ing a reduced thickness (in comparison with thickness of fin 20) to facilitate the suturing of fin 20 to the skin.

Figs. 2, 3, 4 and 6 show the fastener 10 in its open state. Lobes 16 and 18 are joined by hinge 52 at the meeting edge 54 of grippers 28 and 30. Lobes 16 and 18 are thus rotatable through about 270° about hinge 52. Hinge 52 is formed during the moulding of lobes 16 and 18 and is made up of a thin web-like section of material joining lobes 16 and 18.

In the preferred embodiment shown in Figs. 1-7 grippers 28 and 30 comprise outer semi-cylinders 56 and 58 respectively and are lined with liners 60 and 62 respectively. Any soft, easily moldable TPE or silicone could also be used. Liners 60 and 62 provide a surface of relatively high friction to facilitate the gripping of tubing 12. Liners 60 and 62 are hinged by webs 64 and 66 (see Fig. 6) which mate with gaps 68 in hinge 52 and 70 respectively. Gaps 68 and 70 coincide with grooves 44 and 46 respectively. The radius of liners 60 and 62 is slightly smaller than the outside radius of the tube to be fastened so that the tube 12 will be securely gripped. It will be noted that each gripper is formed with a segment of each of grooves 44 and 46 so that when the fixation device 10 is closed the segments of those grooves form circumferential grooves 44 and 46.

In order to locate liners 60 and 62 in grippers 28 and 30, grippers 28 and 30 are provided with slots 80, 82, 84 and 86. Liners 60 and 62 are respectively provided with projections 90, 92, 94 and 96 which fit tightly into slots 80, 82, 84 and 86 respectively (See Fig. 6).

Tab 24 is provided with male snap connector 22a and Tab 26 is provided with female snap connector 22b. When fixation device 10 is closed, connectors 22a and 22b mate releasably and hold tabs 24 and 26 together securely so that tube 12 is gripped by grippers 28 and 30.

While many shapes are possible for tabs 24 and 26, each is preferably a reverse mirror image of the other. This means that when lobes 16 and 18 are brought together and fixation device 10 is in its closed state, there will be a region 72 of fin 20 in which its thickness is 2t and two regions of overlap 74 and 76 where its thickness is t, (where t is the thickness of each of tabs 24 and 26). Suture holes 32 and 34 are placed in tabs 24 and 26 respectively in regions of overlap 74 and 76 to facilitate the disengagement of snap connector 22. These regions can be gripped easily and provide leverage to make it easy to disengage snap connector 22. Another purpose of these regions of overlap is to provide a thin tab to facilitate the suturing of fastener 10 to the skin.

The inner surfaces 60a and 62a of liners 60 and 62 are specially adapted to facilitate the gripping of tubing 12. There are several ways in which this may be achieved. In the preferred embodiment the inner surfaces 60a and 62a of liners 60 and 62 comprise a tacky or clingy material having a thickness preferably varying between 0.482 mm (0.019") and 2.235 mm (0.088") but not less than 0.254 mm. (0.010"). The liner material is

selected for its compatibility with tubing 12. The tacky material must be such that the coefficient of friction of tubing 12 and liners 60 and 62 is high. This allows tubing to be removed easily on opening of fastener 10 if it is necessary, and increases the gripping ability of grippers 28 and 30. The high coefficient of friction between the liners and the tube makes it difficult to pull the tube through fastener 10 when it is in its closed state. Liners 60 and 62 are preferably made of thermoplastic elastomer (TPE), preferably C-Flex 35-A resin, a styrene-block copolymer (comprising polydimethylsiloxane modifiers) available from Concept Polymer Technologies, Inc. of Clearwater, Florida.

The inner surfaces 60a and 62a of liners 60 and 62 are contoured so that if an axial pulling force is applied to tubing 12 a component of that force will be directed at an acute angle to the axial force. Although many contours will provide this effect, a generally sinusoidal contour 78 is preferred as shown in Fig. 7. The contour of surface 60a shown in Fig. 7 corresponds with the curvature of three circles. Surface 61b corresponds with an arc of the circumference of a circle whose center point is located at a point C₁, outside tube holder 38 and half way along the length of tube holder 38. Surfaces 61a and 61c correspond to an arc of the circumference of circles whose center points are respectively located at points C₂ and C₃ and respectively one third of the length of tube holder 38 from the ends of tube holder 38. Surfaces 61d, e and f are similarly contoured to be parallel to surfaces 61a, b and c. A similar effect may be achieved by providing the liners 60 and 62 with protrusions such as ribs or studs 60b and 62b as shown in Fig. 8.

It is possible though not preferred to omit liners 60 and 62. In such an embodiment, as shown in Fig. 8, the inner surfaces of grippers 28 and 30 may be contoured or may be provided with ribs or similar protrusions 78a as shown in Fig. 9.

The fixation device 10 is used by simply placing the tubing longitudinally in one of liners 60 or 62 and closing the fastener by bringing tabs 24 and 26 together. The tabs are releasably fastened to each other by means of snap-connector 22. Thereafter, the fastener is secured to the patient by placing the fin 20 flat on skin 36 and suturing fin 20 to the skin using holes 32 and/or 34. The tubing may be removed by un-snapping connector 22 by grasping overlapping portions 48 and 50. The fixation device is made by conventional injection molding techniques.

Claims

1. A medical device (10) for securing tubing (12) to a patient, the device comprising:

a first elongate semi-cylindrical member (16) and a second elongate semi-cylindrical member (18), the first and second members respectively comprising first (28) and second (30)

elongate gripping channels and first (24) and second (26) tabs secured respectively to first and second gripping channels, the first (24) and second (26) tabs respectively lying lengthwise substantially parallel to the first (28) and second (30) elongate gripping channels; at least one of the gripping channels being provided with an inner gripping surface (60a, 62a) comprising gripping means (61a to 61f; 78; 78a) for gripping the tubing in the absence of undue constriction of the tubing (12) when the members (16, 18) are in a closed position; and connecting means (22) for releasably connecting the tabs (24, 26) such that when the members (16, 18) are in said closed position, the tabs (24, 26) touch each other and the tubing (12) is gripped between the first and second elongate gripping channels (28, 30).

2. The device of claim 1 further comprising a hinge (52) disposed between the first and second members (28, 30) and about which the members (16, 18) can rotate between an open position and the closed position.

3. The device of claim 2 wherein each elongate gripping channel (28, 30) comprises a tab edge and a hinge edge the first (24) and second (26) tabs being respectively secured to the tab edges of the first (28) and second (30) elongate gripping channels and the hinge (52) being secured to the first (28) and second (30) elongate gripping channels at their hinge edges.

4. The device of claim 1 wherein the connecting means (22) comprises connector means (22a, 22b) for releasably joining the first (24) and second (26) tabs when the semi-cylindrical members (16, 18) are in the closed position.

5. The device of claim 1 wherein the first tab (24) comprises a first overlapping portion (48) which overlaps the second tab (26) when the semi-cylindrical members (16, 18) are in the closed position.

6. The device of claim 1 wherein the second tab (26) comprises a second overlapping portion (50) which overlaps the first tab (24) when the semi-cylindrical members (16, 18) are in the closed position.

7. The device of claim 1 wherein the gripping means (60a, 62a) comprise a tacky material.

8. The device of claim 1 wherein the gripping means (60a, 62a) comprise an uneven surface (61a to 61f).

9. The device of claim 1 wherein the gripping means (60a, 62a) comprise a generally sinusoidal surface (78).

10. The device of claim 1 wherein the gripping means (60a, 62a) comprise a plurality of bumps (60b, 62b; 78a).

Patentansprüche

1. Medizinische Vorrichtung (10) zur Befestigung eines Rohres (12) an einem Patienten, wobei die Vorrichtung umfaßt:

ein erstes längliches halbzyndrisches Element (16) und ein zweites längliches halbzyndrisches Element (18), wobei das erste und zweite Element eine erste (28) bzw. zweite (30) längliche Aufnahmerille und eine erste (24) bzw. zweite (26) Lasche umfaßt, die an der ersten bzw. zweiten Aufnahmerille befestigt sind, wobei die erste (24) und zweite (26) Lasche in Längsrichtung im wesentlichen parallel zur ersten (28) bzw. zweiten (30) länglichen Aufnahmerille verläuft; wobei zumindest eine Aufnahmerille mit einer inneren Haltefläche (60a, 62b) versehen ist, die Haltemittel (61a bis 61f; 78, 78a) aufweist, um das Rohr ohne unpassende Einschnürung des Rohren (12) zu fassen, wenn die Elemente (16, 18) sich in geschlossener Stellung befinden; und Verbindungsmittel (22) zum lösbar Verbinden der Laschen (24, 26), sodaß, wenn sich die Elemente (16, 18) in der genannten geschlossenen Stellung befinden, die Laschen (24, 26) einander berühren und das Rohr (12) zwischen den ersten und zweiten länglichen Aufnahmerillen (28,30) festgehalten ist.

2. Vorrichtung nach Anspruch 1, weiter umfassend ein Scharnier (52), welches zwischen dem ersten und zweiten Element (28, 30) angeordnet ist und um welches die Elemente (16, 18) zwischen einer offenen Stellung und der geschlossenen Stellung drehbar sind.

3. Vorrichtung nach Anspruch 2, dadurch gekennzeichnet, daß jede längliche Aufnahmerille (28, 30) von einem Laschenrand und einem Scharnierrand umfaßt ist, wobei die erste (24) und zweite (26) Lasche an den Laschenrändern der ersten (28) bzw. zweiten (30) länglichen Aufnahmerille und das Scharnier (52) an der ersten (28) und zweiten (30) länglichen Aufnahmerille an deren Scharnierrändern befestigt sind.

4. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Verbindungsmittel (22) Verbindersteile (22a, 22b) zum lösbar Verbinden der ersten (24) und zweiten (26) Lasche umfassen, wann sich die halbzyndrischen Elemente (16, 18) in der

geschlossenen Stellung befinden.

5. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die erste Lasche (24) einen ersten Überlappungsabschnitt (48) umfaßt, der die zweite Lasche (26) überlappt, wenn sich die halbzylindrischen Elemente (16, 18) in der geschlossenen Stellung befinden. 5
6. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die zweite Lasche (26) einen zweiten Überlappungsabschnitt (50) umfaßt, der die erste Lasche (24) überlappt, wenn sich die halbzylindrischen Elemente (16, 18) in der geschlossenen Stellung befinden. 10
7. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Haltemittel (60a, 62a) ein klebendes Material umfassen. 15
8. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Haltemittel (60a, 62a) eine unebene Oberfläche (61a bis 61f) aufweisen. 20
9. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Haltemittel (60a, 62a) eine im wesentlichen sinusförmige Oberfläche (78) aufweisen. 25
10. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Haltemittel (60a, 62a) mehrere Erhebungen (60b, 62b; 78a) aufweisen. 30

Revendications

1. Dispositif médical (10) destiné à fixer une tubulure (12) à un patient, le dispositif comprenant :

un premier élément semi-cylindrique allongé (16) et un deuxième élément semi-cylindrique allongé (18), les premier et deuxième éléments comprenant respectivement des première et deuxième gouttières agrippantes allongées (28) et (30) et des première et deuxième pattes (24) et (26) fixées respectivement aux première et deuxième gouttières agrippantes, les première et deuxième pattes (24) et (26) s'étendant respectivement longitudinalement, sensiblement parallèlement aux première et deuxième gouttières agrippantes allongées (28) et (30); au moins une des gouttières agrippantes étant munie d'une surface inférieure agrippante (60a, 62a) qui comprend des moyens agrippants (61a à 61f ; 78 ; 78a) destinés à agripper la tubulure en l'absence d'une constriction excessive de la tubulure (12) lorsque les éléments (16, 18) sont dans une position fermée, et des moyens d'assemblage (22) servant à

assembler les pattes (24, 26) de façon détachable de telle manière que, lorsque les éléments (16, 18) sont dans ladite position fermée, les pattes (24, 26) se touchent et que la tubulure (12) soit agrippée entre les première et deuxième gouttières agrippantes allongées (28, 30).

2. Dispositif selon la revendication 1, comprenant en outre une charnière (52) disposée entre les premier et deuxième éléments (28, 30) et autour de laquelle les éléments (16, 18) peuvent tourner entre une position ouverte et la position fermée. 15
3. Dispositif selon la revendication 2, dans lequel chaque gouttière agrippante allongée (28, 30) comprend un bord côté patte et un bord côté charnière, les première et deuxième pattes (24) et (26) étant respectivement fixées aux côtés patte des première et deuxième gouttières agrippantes allongées (28) et (30) et la charnière (52) étant fixée aux première et deuxième gouttières agrippantes allongées (28) et (30) au droit de leurs côtés charnière. 20
4. Dispositif selon la revendication 1, dans lequel les moyens d'assemblage (22) comprennent des moyens connecteurs (22a, 22b) servant à réunir les première et deuxième pattes (24) et (26) de façon séparable lorsque les éléments semi-cylindriques (16, 18) sont dans la position fermée. 25
5. Dispositif selon la revendication 1, dans lequel la première patte (24) comprend une première portion à recouvrement (48) qui recouvre la deuxième patte (26) lorsque les éléments semi-cylindriques (16, 18) sont dans la position fermée. 30
6. Dispositif selon la revendication 1, dans lequel la deuxième patte (26) comprend une deuxième portion à recouvrement (50) qui recouvre la première patte (24) lorsque les éléments semi-cylindriques (16, 18) sont dans la position fermée. 35
7. Dispositif selon la revendication 1, dans lequel les moyens agrippants (60a, 62a) comprennent une matière adhésive. 40
8. Dispositif selon la revendication 1, dans lequel les moyens agrippants (60a, 62a) comprennent une surface irrégulière (61a à 61f). 45
9. Dispositif selon la revendication 1, dans lequel les moyens agrippants (60a, 62a) comprennent une surface sensiblement sinusoidale (78). 50
10. Dispositif selon la revendication 1, dans lequel les moyens agrippants (60a, 62a) comprennent une pluralité de saillies (60b, 62b ; 78a). 55

FIG-1

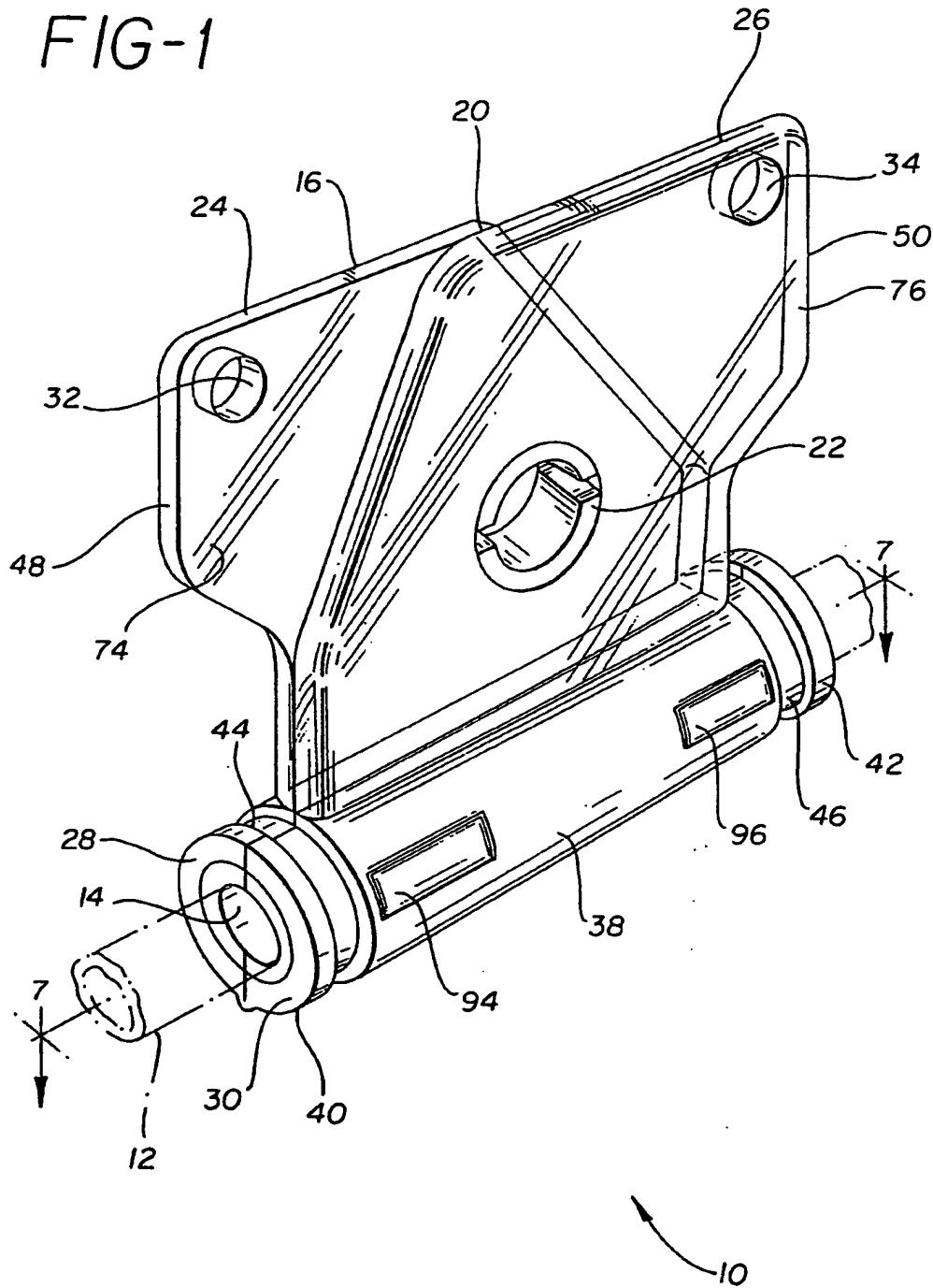


FIG-2

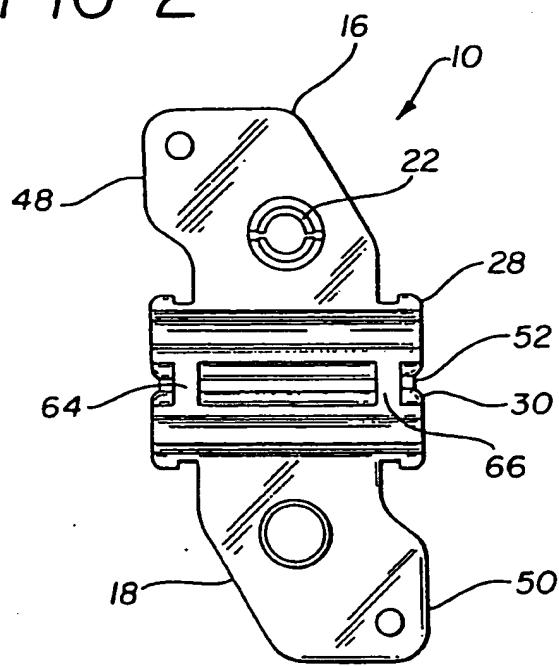


FIG-4

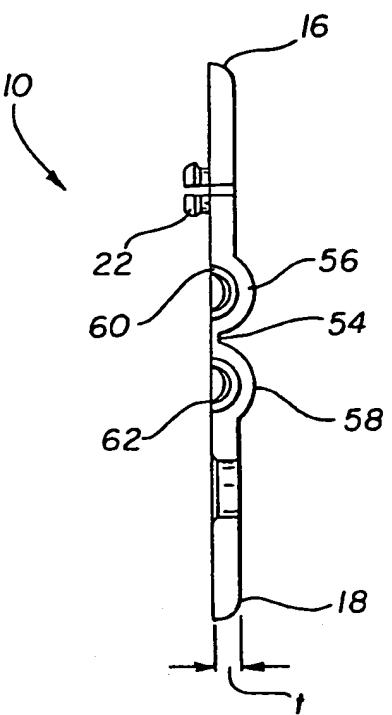


FIG-3

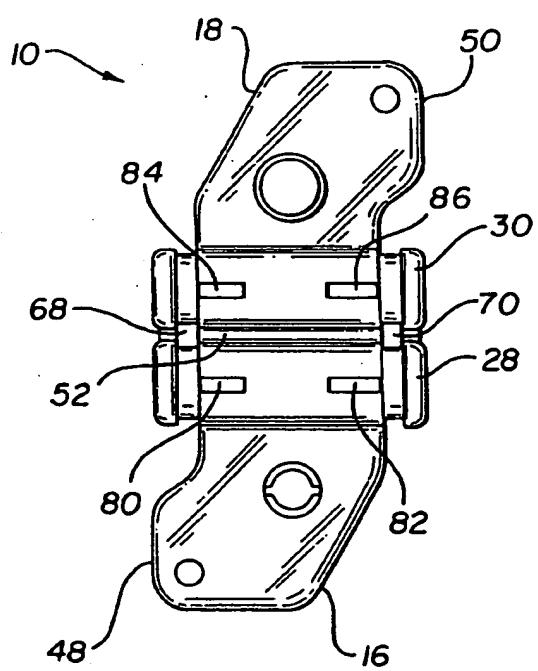
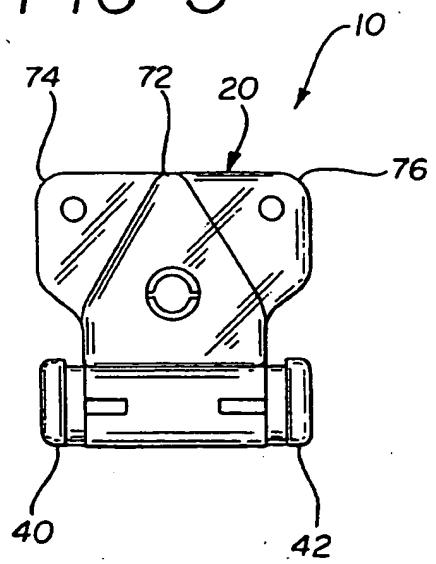
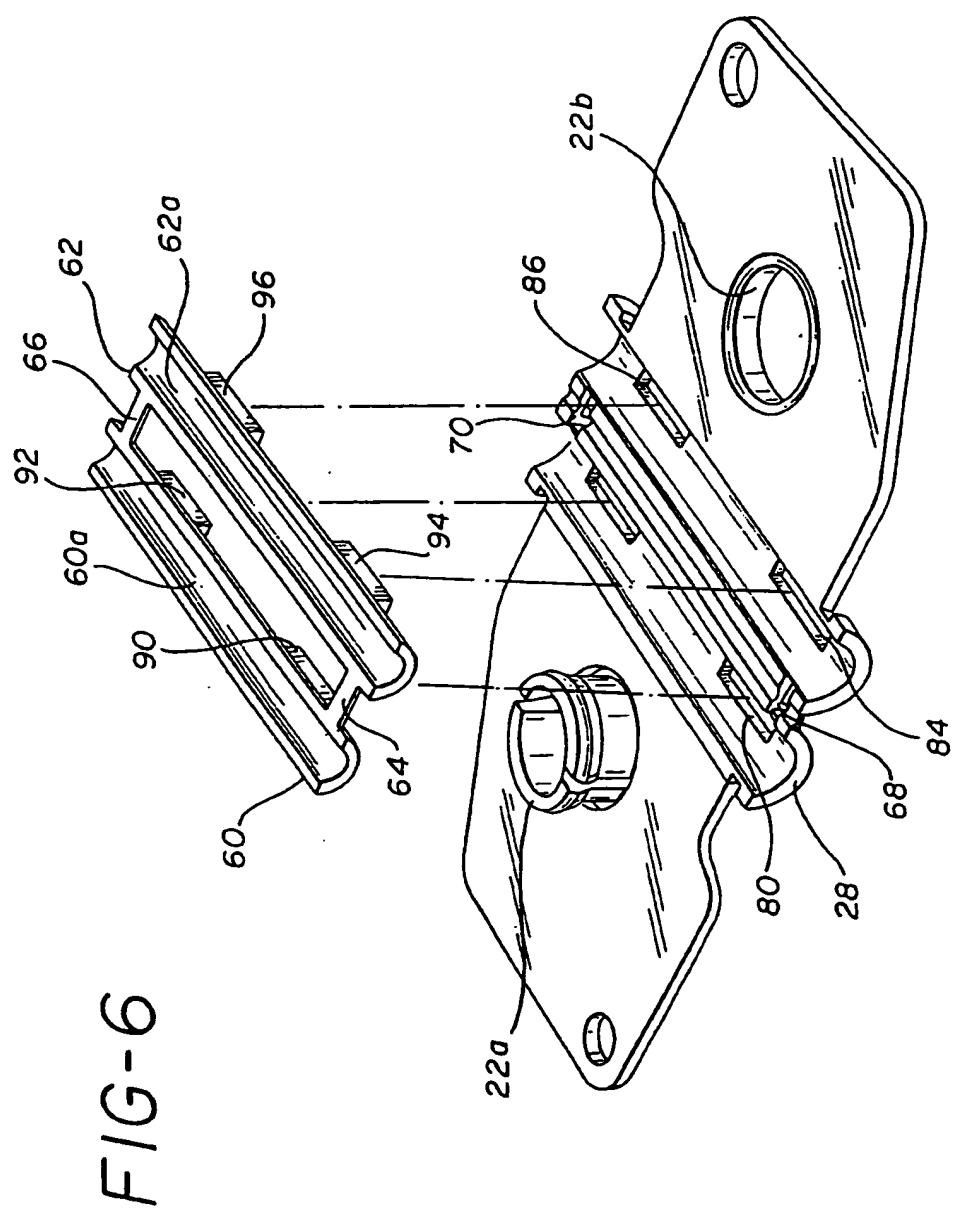
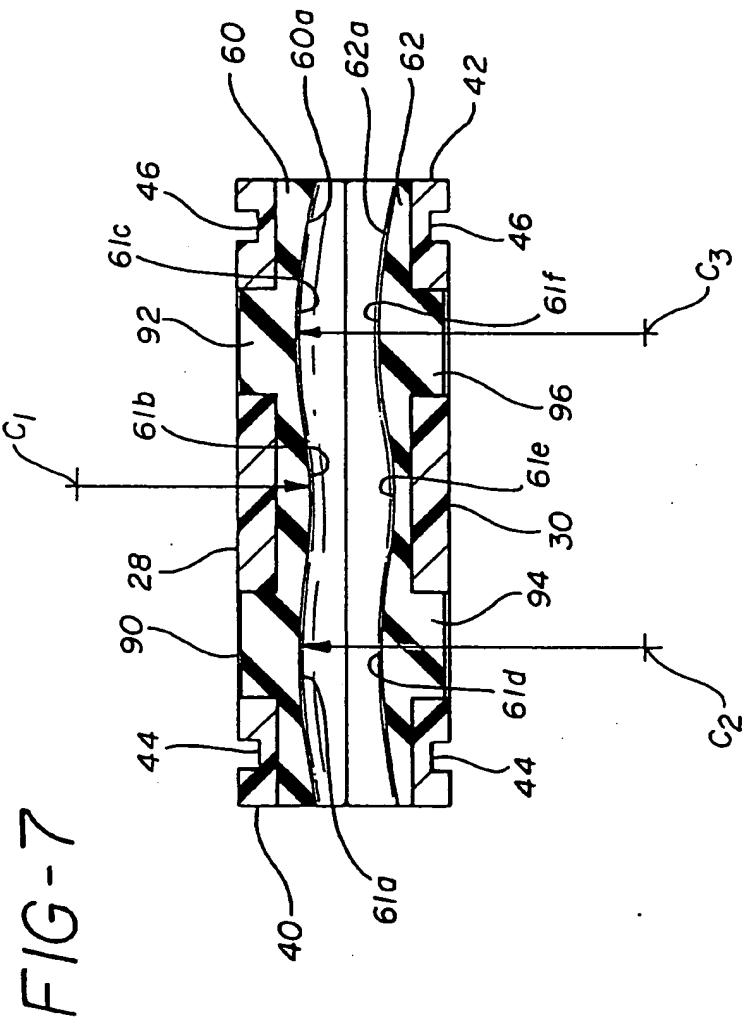


FIG-5







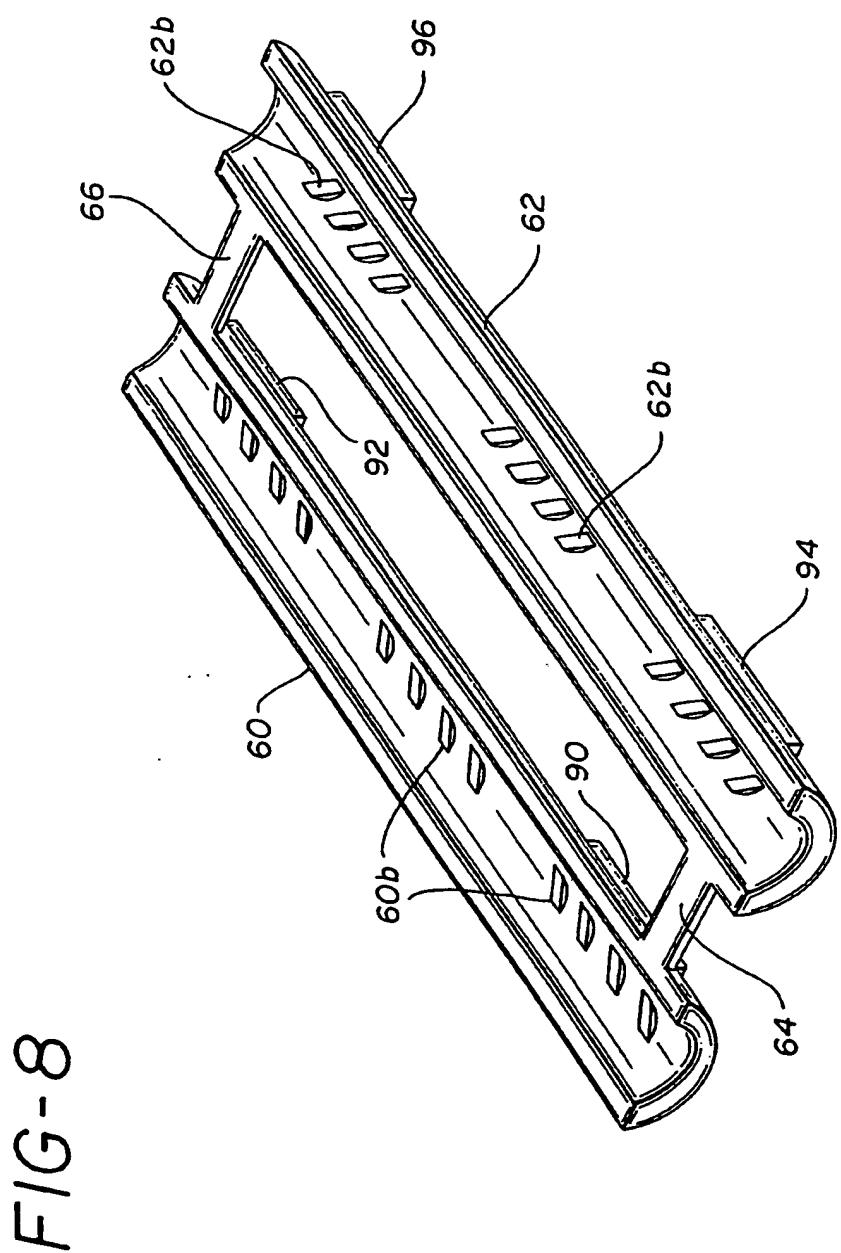
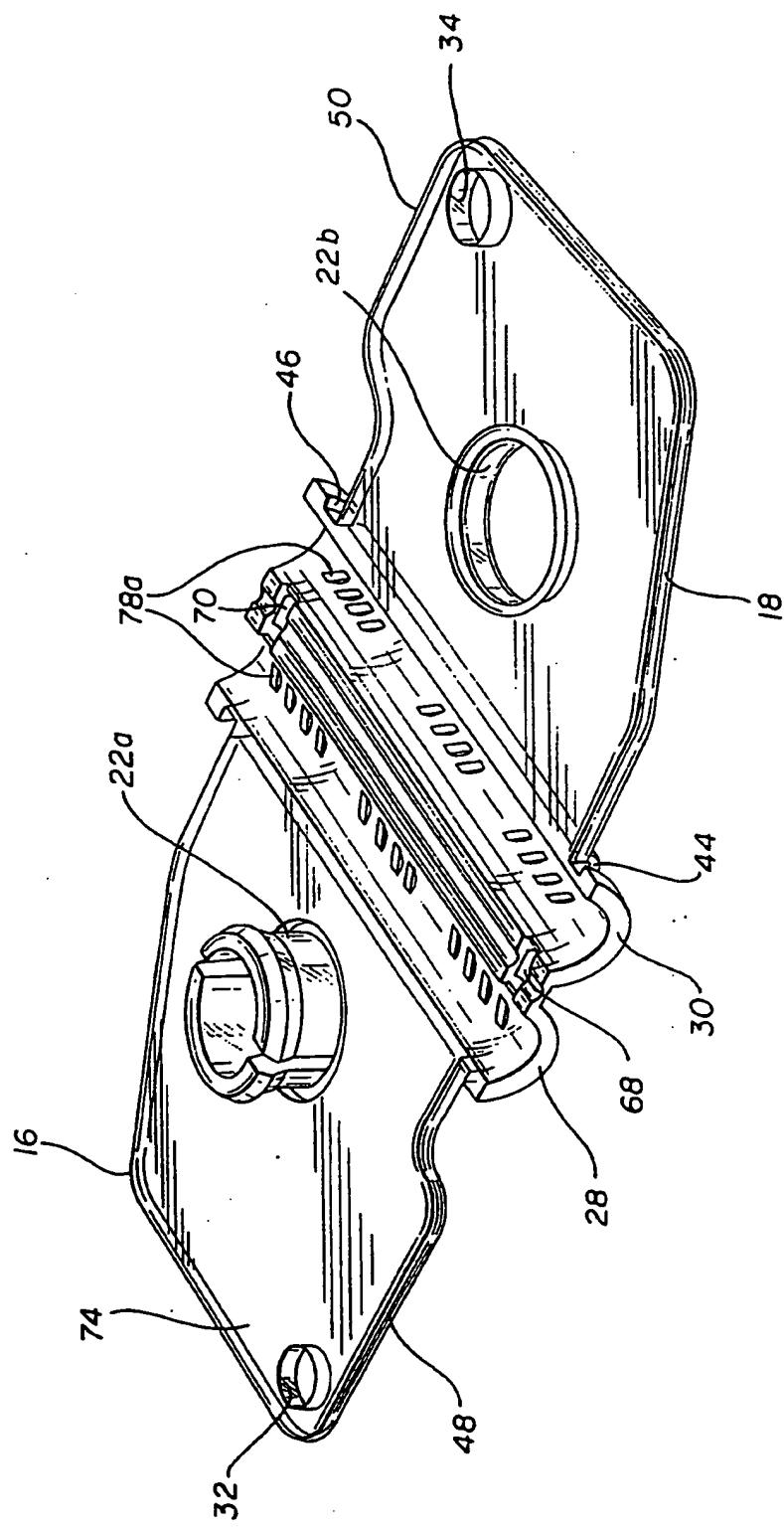


FIG-9



THIS PAGE BLANK (USPTO)